UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,337	11/30/2003	Norman F. Sheppard JR.	95,1408-UUU	5481

7590 12/29/2004

McDonnell Boehnen Hulbert & Berghoff
32nd Floor
300 S. Wacker Drive
Chicago, IL 60606

EXAMINER	
DO, PENSEE T	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/726,337	SHEPPARD ET AL.	
	Examiner	Art Unit	
	Pensee T. Do	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22, 26, 28* is/are rejected.

7)☒ Claim(s) *23-25 and 27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *October 7, 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry & Claim Status

The amendment filed on October 7, 2004 has been acknowledged and entered.

Claims 1-28 are pending.

Withdrawn Rejection(s)

The Double Patenting Rejection is withdrawn due to the filing of a Terminal Disclaimer.

Maintained Rejection(s)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, 5-7, 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Schnipelsky et al. (US 5,229,297).

Schnipelsky teaches a device for detecting DNA. The device comprises a fluid sample entry port which has a platform formed by the two sheets (fig. 2, components 12 & 14), which then lead to a detection chamber 26, such detection chamber is coated with specific binding reagent that binds to the analyte/target (or amplifying reagents); a wash buffer reservoir containing a wash buffer in fluid communication with the detection chamber; a fluid receptacle in fluid communication with the detection chamber; and a reagent chamber for detecting the analyte/particulate in communication with the detection chamber; wherein the fluid sample is moved from the fluid sample entry port to the detection chamber and incubated thereon; wherein the fluid sample is replaced with the wash buffer and displaced into the fluid waste receptacle; and wherein the wash buffer is further displaced into the waste receptacle; and wherein the reagent is added to the detection chamber and particulates/analytes are detected thereon. The label used can be an enzyme or leuco dyes. Leuco dyes can be used for histochemical stains. Leuco dyes can also be used as a fluorescent label. (see col. 6, line 44-col. 7, line 54; col. 9, line 60-col. 10, line 46). The detection compartment is a flow by compartment supported by a supporting sheet. Such sheet can be a porous nylon membrane. (see col. 12, lines 36-65).

Claims 1, 3-22, 26, 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Mian et al. (US 6,319,469).

Mian teaches methods and apparatus for performing microanalytic and microsynthetic analysis. The apparatus is a microsystem platform and a micromanipulation device for manipulating the platform that utilizes centripetal force

resulting from the rotation of the platform to motivate fluid movement through microchannels. The microanalytic system comprises a combination of elements. The first element is a microplatform that is a rotatable structure, most preferably a disk, the disk comprises sample inlet ports, fluid microchannels, reagent reservoirs including wash buffer reservoirs, reaction chambers, detection chambers, waste receptacles and reagent outlet ports. Specific sites on the disk comprise elements that allow fluids to be analyzed, including thermal source, light, particularly monochromatic light, sources, and acoustic sources as well as detectors for each of these effectors. The disk incorporates micromachined mechanical, optical, and fluidic control structures on a substrate that is made from plastic, silica, quartz, metal or ceramic. Sample movement is controlled by centripetal or linear acceleration and selective activation of valves on the disk. Filters and other means for selectively retaining or facilitating passage of particulate matter, including cells, cell aggregates, protein aggregates, or other particulate material comprising fluids are also being applied to the disk. (see col. 16, lines 18-55; col. 17, lines 3-5). The surface of the reaction chamber/cell accumulation chamber is immobilized with an antibody to permit cell/analyte to attach to the surface and be retained in the chamber thereby. In operation, the disk is spun to first introduce the sample into the reaction chamber containing immobilized antibody/reagent, followed by introduction of the second antibody into the reaction chamber after a time sufficient to saturate the immobilized antibody with antigen to the extent that the antigen is present in the sample. Alternatively, the sample may be contacted with a second antibody, allowed to interact, and then introduced into the reaction chamber. After each

incubation, washing buffer from a buffer reservoir is spun into the reaction chamber in order to remove unbound antibody. The extent of enzyme-linked, secondary antibody binding is evaluated by detection of a purple precipitate using a photodiode or CCD camera. In an alternative embodiment the immunological assays of the invention, detection of number of particular cells or cell types in fluids such as blood, urine, amniotic fluid, semen and milk is applied. The microsystem platform comprises a chamber or solid surface on the disk that is prepared to selectively bind the particular cells or cell type. After attachment of the cells to the surface, non-specific binding cells and other components are removed by fluid flow (washing) or centrifugal force. The cells of interest that remain attached to the platform surface or chamber are detected and quantified using means including microscopic, spectroscopic, fluorescent, chemiluminescent, or light-scattering means. (see col. 36-37, line 63). The invention also provides such cells attached to specific surface for toxicity monitoring, such as metabolic monitoring to determine the efficacy of bioactive drugs or other treatments. After washing, cells that remain attached to the surface or chamber are detected and counted. Detection and counting is achieved using fluorescence microscopy. Specific dyes can be used to provide the fluorescent signal for any live cells remaining on the disk. The dye can be added directly to the surface or chamber using a membrane-permanent dye, such as acetoxy-methyl ester dyes. Alternatively, specific antibodies can be linked to such dyes. The analyte detection chamber is optically-transparent. When the detection means comprises a light source, such light source illuminates the platform or the detection chamber. When the detection means is a photodetector, such

photodetector detects light from the light source transmitted through or reflected from the cell accumulation chamber on the platform surface. (see col. 21, line 10-col. 24, line 38; example 9). Contact of the surface with the antibody is followed by contacting the surface with a non-specific blocking protein, such as bovine serum albumin. (see col. 37, lines 18-23).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 6, 8, 9-11, 16, 17, 18, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cathey et al. (US 5,399,486) in view of Mian et al. (US 6,319,469).

Cathey teaches a diagnostic unit which provides a sample port, a channel, which feeds the sample to an incubation area by means of capillary action. The incubation area is underneath an optically-clear window and comprises a lipid membrane, which has optical properties and usually a reagent. A reservoir at the end of the channel downstream from the incubation area receives the sample and waste washes, while on one side of the platform area is a reagent reservoir and on the other side a side-waste reservoir, so that one can move the reagent from the reagent reservoir through the platform area into the side-waste reservoir. Various reagents may be contained within the unit and the necessary liquids added automatically by appropriate instrumentation,

so as to have the assay carried out automatically, without technician involvement, providing an accurate and sensitive determination. The wash buffer is introduced into the incubation area through the sample port and flows through the channel to the platform, displaces the sample and the sample and buffer exit into the top waste reservoir. The incubation area is designed to accept a broad range of sample volume of about 10 ul to 250 ul. The top waste reservoir acts as an overflow reservoir when the sample is first flown into the incubation area. The reagent reservoir comprises labels such as enzyme, fluorescer, and a quencher, a dye that absorbs light. The label reagent comprises a member of a specific binding pair. The specific binding member can be an antibody. (see col. 1, line 55-col. 2, line 20; col. 3, line 15-col. 4, line 50; col. 8, lines 8-col. 23).

However, Cathey fails to teach a wash buffer reservoir.

Mian et al. has been described above to teach a wash buffer reservoir.

It would have been obvious to one of ordinary skills in the art to add a wash buffer reservoir in fluid communication with the sample entry port as taught by Mian to the apparatus of Cathey to obviate the need for external apparatus for adding the wash buffer because Cathey teaches that the device unit can have necessary liquids added automatically by appropriate instrumentation to perform an automatic assay. Thus, the sample port can act as a connecting channel for the wash buffer reservoir since the wash buffer reservoir is added to the incubation area through the sample port.

Allowable Subject Matter

Claims 23-25, 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed October 07, 2004 have been fully considered but they are not persuasive.

Regarding the 102(b) by Schnipelsky, Applicant argues that Schnipelsky teaches an apparatus for using PCR technology to amplify and detect DNA, recognized in the art as molecules while the present invention is directed to analyzing particulates such as cells which are orders of magnitude larger and have different fluid flow and other physicochemical properties than the DNA molecules described in Schnipelsky. The instant claims positively recite an apparatus for detecting a particulate in a fluid comprising a detection chamber comprising an area that is coated with a specific binding reagent that specifically binds to the particulate to be detected. The Schnipelsky reference does not teach specific binding to a particulate (such as a cell). For this lack of teaching, Schnipelsky does not anticipate the pending claims.

Regarding the Mian reference, Applicants also submit that Mian does not anticipate the claimed invention because Mian fails to teach the claimed apparatus comprises " a detection chamber comprising an area that is coated with specific binding reagent that specifically binds to the particulate to be detected.".

Cathey fails to specifically mention detection of a particulate, such as cell. Cathey also fails to disclose a detection chamber comprising an area that is coated with a

specific binding reagent that specifically binds to the particulate to be detected. The Mian does not render this deficiency, thus the combination of Mian and Cathey does not render obvious the claimed invention.

The following response is for all the references, Schnipelsky, Mian and Cathey, since Applicants submit that these references lack the same feature, an apparatus for detecting a particulate, and a detection chamber coated with a specific binding reagent. In response to applicant's argument that the apparatus of the prior art is not used for detecting a particulate, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Since the invention is an apparatus, regardless of what its use is, as long as the prior arts discloses the same structurally components as those of the apparatus of the present invention, the prior arts are applicable because with the same components, the apparatus would be able to perform the same functions/utilities.

Regarding the argument that the prior art lacks the teaching of a detection chamber coated with a specific binding reagent, Schnipelsky teaches that detection involves the use of conventional materials capable of bonding via a complementary sequence of nucleotides to a replicated DNA strand. Such materials also include appropriate means that can be used to trap and hold the DNA at the detection site, such as in a detection chamber/compartment. Such appropriate means feature a membrane

and/or a bead that is trapped. Detection requires an immobilizing material and a signal generating material. For example, a primer used to replicate DNA is biotinylated, so as to react with avidin that is attached to the immobilizing material or the signal-generating material (such as a bead). (see col. 6, lines 38-50).

Mian teaches that the surface of the reaction chamber/cell accumulation chamber is immobilized with an antibody specific for an antigen to permit cell/analyte/antigen to attach to the surface and be retained in the chamber thereby. (see col. 36, lines 22-25).

Cathey teaches, on col. 5, lines 40-45, that after a sufficient time for substantially complete reaction of the analyte in the incubation area/detection chamber, so that the member of the specific binding pair present in the sample, the analyte, can bind to ***the complementary member of the membrane or reagent*** which are equivalent to the specific binding reagent (in the incubation area), the incubation area, particularly the lipid membrane may then be washed. Cathey also teaches that the analytes can be any type of compound, such as small organic molecules, proteins, peptides, sugars, lipids and combination thereof, naturally occurring or synthetic as long as there is a complementary binding member. The analytes include components of blood, tissue components and the like. It is inherently taught that tissue components include cells. (see col. 3, line 50-col. 4, line 21).

Concerning the Mian reference, Applicants inform that the assignee listed on the face of Mian is incorrect and the Applicants are correcting this error.

Applicants are required to provide evidence that the Mian reference has common ownership as the present application. Only until then, the 103 rejection would be dropped.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
December 16, 2004

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641
12/22/04